IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA)
)
VS.) NO. H-11-CR-535
) August 18, 2011
FREDDA BRANYON)

REARRAIGNMENT
BEFORE THE HONORABLE MELINDA HARMON

For the Government: Mr. Sam Louis, AUSA
U. S. Attorney's Office
910 Travis, Suite 1500
Houston, Texas 77002

For the Defendant: Ms. Christine Whalin
Law Office of David M. Cantor
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Court Reporter: Bruce Slavin, RPR, CM

Proceedings reported by mechanical stenography and produced by computer-aided transcription.

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THE COURT: The next case is United States v. Fredda Branyon, Criminal No. 11-535.

MR. LOUIS: Sam Louis for the United States, Your Honor. Good morning.

THE COURT: Good morning.

MS. WHALIN: Good morning, Your Honor. Christine Whalin on behalf of Miss Branyon.

THE COURT: Good morning.

All right. It's my understanding that Miss Branyon wishes to enter a plea of "guilty" to a criminal information. Is that correct?

MR. LOUIS: That's correct, Your Honor.

MS. WHALIN: That's correct, Your Honor.

THE COURT: Miss Tippen, would you swear her in, please.

(Defendant sworn)

THE COURT: Ms. Branyon, I believe you understand you are now under oath and that if you answer any of my questions falsely your answers may later be used against you in another prosecution for perjury or making a false statement.

THE DEFENDANT: Yes, ma'am.

THE COURT: What is your full name, please?

THE DEFENDANT: Fredda Lynne Brandon.

THE COURT: And how do you pronounce your last name, again?

THE DEFENDANT: "Branyon".

THE COURT: "Branyon"?

THE DEFENDANT: Yes, ma'am.

10:58 THE COURT: The "D" is silent?

THE DEFENDANT: "B" like "boy".

THE COURT: No. I mean, there is a "D" in the middle of your name.

MR. LOUIS: That's a typo on the docket sheet.

10:58 THE COURT: That's a typo on the docket sheet.

MR. LOUIS: Yes.

THE COURT: So, it's "Branyon".

MR. LOUIS: Yes. On the criminal information it's correct.

10:58 THE COURT: How old are you, please?

THE DEFENDANT: 57.

THE COURT: And what is your educational background?

THE DEFENDANT: High school, college and then

10:58 graduate school.

THE COURT: Okay. And what is your graduate degree in?

THE DEFENDANT: Naturopathic medicine.

THE COURT: And where did you go to school?

10:58 THE DEFENDANT: Southwest School of Naturopathic

Medicine in Tempe, Arizona.

THE COURT: Have you been treated recently for any mental illness or addiction to narcotic drugs of any kind?

THE DEFENDANT: No, ma'am.

10:59 THE COURT: Are you currently under the influence of any drugs or medication or alcoholic beverage of any kind?

THE DEFENDANT: No, ma'am.

THE COURT: Now, you have previously -- I guess

10:59 this morning, just a little bit ago -- you waived your right to be indicted, is that correct --

THE DEFENDANT: Yes, ma'am.

THE COURT: -- before the magistrate judge?

THE DEFENDANT: Yes, ma'am.

10:59 THE COURT: And you understand that you do have the right to be indicted by a grand jury. Is that correct?

THE DEFENDANT: Yes, ma'am.

THE COURT: But you're waiving that right --

THE DEFENDANT: Yes, ma'am.

10:59 THE COURT: -- in order to proceed and plead "guilty" to a criminal information. You understand that?

THE DEFENDANT: Yes, ma'am.

THE COURT: Okay. Have you had a chance to read over the criminal information?

10:59 THE DEFENDANT: Yes, ma'am.

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THE COURT: And have you discussed it with your attorney, Ms. Whalin?

THE DEFENDANT: Yes, ma'am.

THE COURT: Do you feel you understand what it is you have been accused of?

THE DEFENDANT: Yes, ma'am.

THE COURT: Are you fully satisfied with the counsel, representation and advice given to you in this case by Ms. Whalin, your attorney?

11:00

THE DEFENDANT: Yes, ma'am.

THE COURT: I understand there's a plea agreement. Is that correct?

MS. WHALIN: Yes, ma'am.

THE COURT: Mr. Louis, tell us what the terms of the plea agreement are, please.

11:00

MR. LOUIS: Yes, Your Honor. The Defendant is pleading "guilty" to Count 12 of the criminal information, and this agreement is pursuant to Federal Rule of Criminal Procedure 11(c)(1)(A), and at the conclusion of the sentencing the government will file a motion to dismiss the remaining counts of the indictment. Miss Branyon is waiving her right to collaterally attack the sentence or appeal her sentence, except she may appeal a sentence above the statutory maximum or an upward departure that has not been requested by the United States.

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THE COURT: Miss Branyon, does that sound like a fair and accurate summary of the written plea agreement that you propose to enter into this morning?

THE DEFENDANT: Yes, ma'am.

11:00 THE COURT: Have you had a chance to read over the plea agreement?

THE DEFENDANT: Yes, ma'am.

MR. LOUIS: And have you discussed it with Ms. Whalin, your attorney?

11:01 THE DEFENDANT: Yes, ma'am.

THE COURT: Do you feel you understand what it is you're agreeing to do under the plea agreement?

THE DEFENDANT: Yes, ma'am.

THE COURT: And do you feel you understand what it 11:01 is the government is agreeing to do under the plea agreement?

THE DEFENDANT: Yes, ma'am.

THE COURT: Do you have any questions you would like to ask about it at this time?

11:01 THE DEFENDANT: No, ma'am.

THE COURT: Okay. Has anybody made any other or different promises or assurances to you that prompted you to enter a plea of "guilty" that didn't get written down in your written plea agreement?

11:01 THE DEFENDANT: No, ma'am, just these.

THE COURT: Just the ones in the written plea agreement?

THE DEFENDANT: Yes.

THE COURT: Okay. Do you understand that the terms 11:01 of the written plea agreement will be binding upon you and upon the government, but they're not binding upon me?

THE DEFENDANT: Yes, ma'am.

THE COURT: So, it could be that at the time of sentencing the government makes motions and recommendations 11:01 to me, but I'm not required to follow those recommendations or grant those motions. Do you understand that?

THE DEFENDANT: Yes, ma'am.

THE COURT: And, if I don't, you could get a more severe sentence than you would otherwise receive. Do you 11:01 understand?

THE DEFENDANT: Yes, ma'am.

THE COURT: And, if that should happen, do you understand you will not be given an opportunity to withdraw your plea of "guilty"?

11:02 THE DEFENDANT: Yes, ma'am.

THE COURT: Has anyone in any way attempted to force you to plead "guilty" in this case?

THE DEFENDANT: No, ma'am.

THE COURT: Are you pleading "guilty" because you 11:02 are guilty?

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THE DEFENDANT: Yes, ma'am.
THE COURT: Do you understand that the offense to which you are pleading "guilty" is a felony offense?
THE DEFENDANT: Yes, ma'am. Now I do.
THE COURT: And that if your plea is accepted you will be adjudged guilty of that offense?
THE DEFENDANT: Yes, ma'am.
THE COURT: And such adjudication may deprive you of valuable civil rights, such as the right to vote, the right to hold public office, the right to serve on a jury and the right to possess firearms?
THE DEFENDANT: Yes, ma'am.
THE COURT: Are you a U.S. citizen?
THE DEFENDANT: Yes, ma'am.
THE COURT: I want to go over with you now the maximum possible penalties you're facing as a result of your plea of "guilty" this morning.
You are pleading "guilty" to Count 12 of a criminal information which charges you with "introduction of unapproved new drug into interstate commerce", which is a violation of 21, United States Code, Section 331(d). The penalty for that crime is imprisonment not to exceed three years and/or a fine not to exceed $10,000. Along with that there would be supervised release.
Is that correct, Mr. Louis?

MR. LOUIS: That's correct, Your Honor.

THE COURT: And along with that supervised release there will be certain conditions of supervised release that you will be obliged to follow. If you fail to follow those you could be put back into prison for some additional period of time without any credit for the time you have been on supervised release, without any credit for the time you have been in prison, and there would be a one-hundred-dollar special assessment for the one count you're pleading "guilty" to. Do you understand --

THE DEFENDANT: Yes, ma'am.

THE COURT: -- that all of those taken together --

THE DEFENDANT: Yes, ma'am.

THE COURT: -- the prison time, the fine, the supervised release, the conditions of supervised release and the special assessment -- those are the maximum possible penalties you're facing as a result of your plea of "guilty" this morning?

THE DEFENDANT: Yes, ma'am.

THE COURT: Under the Sentencing Reform Act of 1984 the United States Sentencing Commission has issued guidelines for judges to follow to determine what the sentence will be in a criminal case. Have you and Ms. Whalin talked about how the guidelines may apply in your case?

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THE DEFENDANT: Yes, ma'am.

THE COURT: Do you understand that today I will not be able to tell you what your guideline sentence is?

THE DEFENDANT: Yes, ma'am.

THE COURT: And that, because even though the guidelines are no longer mandatory but are advisory, I am still required to consider the guidelines when I determine what the sentence will be in a criminal case. Do you understand that?

THE DEFENDANT: Yes, ma'am.

THE COURT: And in order for me to consider the guidelines I must ask a probation officer to do an investigation on your case and to write a presentence report that will assist me in sentencing. Do you understand that?

THE DEFENDANT: Yes, ma'am.

THE COURT: Once that report has been completed you and Ms. Whalin will get a copy, Mr. Louis, the government's attorney will get a copy, and each of you will be given an opportunity to make any objections you may have to the presentence report. Do you understand that?

THE DEFENDANT: Yes, ma'am. Thank you.

THE COURT: And then we will have a sentencing hearing, and at that hearing I will rule on any objections that may be made to the presentence report. I will also rule on any motions that may be made, recommendations that may be made or any other matters that might be brought to my attention that might have an impact on the sentence you receive. Do you understand that?

THE DEFENDANT: Yes, ma'am.

11:05 THE COURT: And then at the conclusion of that sentencing hearing I will pronounce sentence, you understand.

THE DEFENDANT: Yes, ma'am. Thank you.

THE COURT: And at that time, when I give you your 11:05 sentence, it could be that your sentence is more severe than the one that you and Ms. Whalin may have estimated you might get when you were talking about how the guidelines might apply in your case. Do you understand that?

THE DEFENDANT: Yes, ma'am.

11:05 THE COURT: If that should occur, if your sentence is more severe than the one that you're expecting, do you understand you will not be given the opportunity to withdraw your plea of "guilty"?

THE DEFENDANT: Yes, ma'am.

11:05 THE COURT: Do you also understand that after your guideline range has been determined the Court would have the authority to depart from the guidelines and to impose a sentence that is either more severe or less severe than the sentence called for by the guidelines?

11:06 THE DEFENDANT: Yes, ma'am.

THE COURT: Do you also understand that in the federal system parole has been abolished and that if you are sentenced to prison you will not be released on parole?

THE DEFENDANT: Yes, ma'am.

11:06 THE COURT: And do you further understand that under some circumstances you or the government would have the right to appeal any sentence that I impose?

THE DEFENDANT: Yes, ma'am.

THE COURT: But do you understand that by entering
11:06 into this written plea agreement you will be waiving or giving up virtually any right you have to appeal any sentence that I impose?

THE DEFENDANT: Yes, ma'am.

THE COURT: And that would include not just a
11:06 direct appeal of your conviction and your sentence but, also, a collateral attack, such as a habeas corpus application. Do you understand that?

THE DEFENDANT: Yes, ma'am.

THE COURT: Do you also understand the government
11:07 is not waiving its rights to appeal any sentence I impose?

THE DEFENDANT: Yes, ma'am.

THE COURT: Do you understand you have a right to plead "not guilty" to any offense charged against you?

THE DEFENDANT: Yes, ma'am.

11:07 THE COURT: And do you further understand that by persisting in a plea of "not guilty" you would have a right to a trial by jury or by judge?

THE DEFENDANT: Yes, ma'am.

THE COURT: And at that trial you would have the right to the assistance of counsel in your defense, you would have the right to see and hear all the witnesses and have them cross-examined in your defense, you would have the right on your own part to decline to testify unless you voluntarily elected to do so in your own defense, and you would have the right to the issuance of subpoenas, compulsory process, to compel the attendance of witnesses to testify in your defense?

THE DEFENDANT: Yes, ma'am.

THE COURT: All right. Do you further understand that at the trial the jury would be told that they must presume that you were innocent of any crime charged against you until such time, if ever, the government brought to them evidence that convinced them beyond a reasonable doubt that you were guilty?

THE DEFENDANT: Yes, ma'am.

THE COURT: And do you further understand that at the trial the jury would be told that you had a right not to testify or put on any evidence and they would be told that, if you decided not to testify or put on any evidence, they could not hold that against you as some indication or evidence that you were guilty?

THE DEFENDANT: Yes, ma'am.

THE COURT: And do you further understand that at the trial the jury would be told that they could not expect you to testify, they could not expect you to put on any evidence, they could not expect you to explain yourself or to prove your own innocence?

THE DEFENDANT: Yes, ma'am.

THE COURT: Do you further understand that by entering a plea of "guilty", if that plea is accepted by the Court, that there will be no trial? You will have waived or given up your right to a trial as well as all the other rights that I have outlined for you that go along with a trial by jury or judge? Do you understand that?

THE DEFENDANT: Yes, ma'am.

THE COURT: Do you waive reading of the indictment?

MS. WHALIN: Yes, Judge.

THE COURT: I'm sorry. The criminal information. Excuse me.

All right. I want to go over with you now, Ms. Branyon, the essential elements of Count 12, which is the count you're pleading guilty to, because I want to be sure you understand what it is you're pleading "guilty" to.

THE DEFENDANT: Yes, ma'am.

THE COURT: Now, by "essential elements" I mean what it is the government would have to prove to a jury beyond a reasonable doubt before that jury could find you guilty. Okay?

The essential elements of "introduction of unapproved new drug into interstate commerce" are as follows: First, that the Defendant -- you, Ms. Branyon -- introduced and caused the introduction into interstate commerce of a drug; second, the drug was an unapproved new drug; and, third, that you did so with the intent to defraud and mislead.

Do you understand those are the essential elements of the crime you're pleading "guilty" to this morning?

THE DEFENDANT: Yes, ma'am.

THE COURT: Mr. Louis, would you tell me what it is the government is prepared to prove if we went to trial in this case.

MR. LOUIS: Yes, Your Honor. The essential elements -- or the essential facts of this case are that beginning in or about April of 2009 the Defendant was an owner of a company called Global Laboratories, LLC, which was located at 28150 North Alma School Parkway, Suite 103, in Scottsdale, Arizona. Global Laboratories was an entity that mainly focused on the manufacture, sale and distribution of stem cells. Global Laboratories, however, was not a facility that was approved by the FDA to manufacture, market or distribute biological or drug products. Stem cells under the Food, Drug and Cosmetic Act are both biological and drug products. That's also a biological product under the Public Health Services Act.

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In December of 2008 the Defendant acquired a company called Caledonia Consulting. This company, Caledonia, also focused on the manufacture, sale and distribution of stem cells. After acquiring Caledonia the Defendant changed the name of that company to "Global Laboratories".

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During the same time period the Defendant was the owner of a medical center facility called "New Hope". It was located at 8390 East Via de Ventura, Suite F-204, in Scottsdale, Arizona. The Defendant was often referred to as "Dr. Branyon" and utilized that designation. She received a degree in naturopathic medicine from the Southwest College of Naturopathic Medicine and Health Sciences which is located in Arizona. However, that degree did not bestow upon her the ability to perform medical procedures.

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New Hope focused on the treatment of autoimmune diseases such as cancer and chronic diseases for which the treatment of stem cells occurs. The Defendant later changed the name of New Hope to "Branyon Integrated Medicine". In addition, the Defendant operated several web

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sites that were associated with the medical facility that focused and discussed stem cells to treat these autoimmune and chronic diseases, including amyotrophic lateral sclerosis, also known as "ALS", and multiple sclerosis, known as "MS."

11:12 Sometime in April of 2009 the Defendant was contacted by an individual identified as "FM" regarding the purchase of stem cells from Global Laboratories. "FM" indicated that he was a physician with Rio Valley Medical Clinic located in Brownsville, Texas, and also the director of stem cell research with the Instituto Politecnico Nacional School of Medicine in Mexico City, Mexico. "FM" had previously purchased stem cells from prior owners of Caledonia Consulting, Inc.

11:13 After brief negotiations with "FM" on April 6 of 2009 the Defendant sold 16 vials containing stem cells derived from cord blood to "FM". The vials were sent by -- it says "UPS" -- I think it should be "USPS", United States Postal Service -- from Global Laboratories, LLC, to "FM" in Brownsville, Texas.

11:13 MS. WHALIN: That is "UPS".

MR. LOUIS: That is "UPS"? Okay.

"FM", in turn, used these stem cells in connection with medical procedures he performed on patients suffering from ALS and MS.

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At the time of this transaction the Defendant and "FM" were aware that the United States Food and Drug Administration had not approved the use of stem cells in connection with the treatment of patients suffering from incurable autoimmune diseases such as ALS and MS. The FDA had approved the use of stem cells for research purposes only and under strict guidelines which require FDA approval. The stem cells were described as eight mesenchymal vials and eight progenitor vials.

In connection with the sell of the stem cells the Defendant provided "FM" with a form indicating that the sell of the stem cells was for research purpose only. However, the Defendant knew that "FM" would be using the stem cells to treat patients in Mexico.

Subsequent to the initial sale of stem cells to "FM" the Defendant sold approximately 183 vials containing stem cells to "FM" on 27 separate occasions during the period of April 6, 2009, through February 1st, 2010. The stem cells were derived from umbilical cord blood.

Investigation into the activities of "FM" indicated that "FM" was not licensed to practice medicine in any state or territory of the United States and did not work at a medical facility in Brownsville, Texas, or anywhere else in the United States. The Defendant received approximately 300,000 for the sale of the stem cells.

In order to maintain and replenish stem cells Global Laboratories -- in order to maintain and replenish Global Laboratories' inventory of stem cells, the Defendant began purchasing umbilical cord tissue from a birthing facility operated by "AR" in Del Rio, Texas. "AR" was a licensed midwife who delivered babies at the clinic and obtained umbilical cord tissue and cord blood from new mothers after the birth of the child. AR would inquire if new mothers would be willing to donate their umbilical cord and cord blood tissue for research. "AR" would have new mothers then execute a form indicating the tissue would be donated for research. This form was provided to "AR" by the Defendant. The umbilical cord tissue, however, was then provided to the Defendant by "AR" for the purpose of creating stem cells.

The Defendant began purchasing the cord blood tissue from "AR" on August 18th of 2009, which continued through January of 2010. This cord blood or cord blood tissue was sent from Del Rio, Texas, to the Defendant, and the Defendant would pay "AR" for the stem cell -- for the cord blood tissue.

The Defendant had no formal training regarding the creation of stem cells and hired "VD", a medical school professor in Columbia, South Carolina, as a consultant.

"VD" was a research professor who would travel to Scottsdale, Arizona, on occasions to review efforts of others associated with Global Laboratories in the creation of stem cells from umbilical cord tissue. "VD" would examine and review stem cells created from cord blood while conducting research at the medical school. The Defendant on more than one occasion would also send cord blood to "VD" in South Carolina to examine and determine the viability of stem cells. "VD" did create viable stem cells which were then provided to the Defendant. These stem cells were created with the intention of being utilized in the treatment of individuals suffering from diseases such as ALS and MS. These stem cells were not created in any FDA-approved laboratory or under FDA guidelines.

THE COURT: Miss Branyon, can you tell me in your own words what it is you did to commit the crime you're pleading "guilty" to this morning?

THE DEFENDANT: Yes, ma'am. I bought a lab that was using stem cells for about six years and I bought the lab and they -- I believed them. And after I bought the lab, when they wouldn't give me the SOPs that I thought I was supposed to get, I kind of wondered --

THE COURT: What are "SOPs"?

THE DEFENDANT: Standard operating procedures books. Lots of them.

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THE COURT: All right.

THE DEFENDANT: And when I realized that something wasn't right there -- They always told me that it was not FDA-approved. I knew that. But they always said that it was a gray area and that, as long as you did it correctly and I did everything the way they told me to do -- the material transfer agreement, everything....

But when I started trying to get the lab FDA-approved in Scottsdale, after I bought the lab, I had brought in fire department men to -- because you have to start with the building, and the building didn't go with the code. So, we were trying to move and I was trying to get everything correct. I even asked a lab -- he investigates labs, and I even asked him what to do. Evidently, he didn't realize, because he told me as long as we were just doing everything and -- I thought that was okay.

But then, right when we found out we had to move -- We found a building and we moved everything over, all the equipment over, and then I realized that we -- I was learning in all of this process because I was so ignorant I -- I listened to too many people that gave me the wrong -- I'm guilty. I'm guilty.

And, so, once I realized it was going to be a lot more steps, then all of this happened with Mr. -- Dr. Morales, but we had already stopped everything because

11:20 we didn't have the ability to do anything. But let me back up.

I did get cord blood from Dr. Ramon, and it is customary in the United States to give donations to the doctors for their work. So, I didn't think I was buying it, but I guess it's the same thing.

11:21 So, when we -- I never created -- I'm not -- I don't -- I'm not that smart. I am a business owner, and I thought I was helping the world by getting this started. But I never created them, but the people who owned the lab before me -- There were, from what I understand, two people, a female from Harvard and a man from Charleston, South Carolina, or Columbia, the medical university there, and they brought him out to kind of show us what to do, but we

11:21 couldn't do it without -- You can't come in and show somebody to do something and go away. It's not possible.

So, I was trying to recoup my money because I knew I had been scammed with -- I am getting off....

11:21 So, anyway, when I got the cord blood from Dr. Ramon I would pull blood and send it to the lab to make sure there was no HIV or anything so that I could send it on to Vincent, because I felt that I should at least, before I give anything, make sure there's no disease or anything for

11:22 anybody to handle. So, when he got it, he would either tell me, 'Oh, it's bad blood' or 'Yeah, we can do it,' or something.

But, in the meantime, he and I agreed that we would do a new corporation, Biostem Genetics Corporation, and that we would -- So, we went to an attorney to get all of the paperwork done and everything, but we never actually started it, thank goodness. So, what blood that he said we could, he would send -- he would make the stem cells and send back to me, and I would store them in liquid nitrogen, and were basically trying to get our stock ready for the new company, which was going to be, hopefully, FDA-approved and a real lab.

Does that make sense? I didn't really know I was doing so wrong, but I am guilty.

THE COURT: Well, okay. Let me ask you this.

THE DEFENDANT: Yes, ma'am. I know.

THE COURT: "I didn't really know what I was doing was so wrong." Does that mean that you didn't know that you were violating the law to some extent?

THE DEFENDANT: I knew that it was -- Everybody always told me it was a gray area. So, whenever we -- like with Dr. Morales, when I sold to him, he always told me he did it in Mexico and it's legal in Mexico. So, I just didn't even worry about it. And then, when everything was done, it was always done in Mexico, because I did know that there was a gray area, because I was always understanding that there wasn't a law against it or for it. I knew that the government was doing grants with embryonics and we were doing umbilical. Embryonics is bad, and I knew that they were doing grants and research with embryonics, but never have they done any research with umbilical, and umbilical has been done since 1962. There's never been a death. There's never been a bad complication or anything. And I didn't realize -- I just thought we were bringing something wonderful to the world. I thought we were going to -- I thought I was in God's will, and I am still wondering how I could have done all this -- how did I miss the point.

THE COURT: Can you tell me why you're pleading "guilty"?

THE DEFENDANT: Why am I pleading "guilty"? Because I did sell stem cells. I did do that, I did sell them, and now I find out that it's against the law.

THE COURT: If the case went to trial the government would have to prove -- one of these elements, that is -- what you did was with the intent to defraud and mislead.

THE DEFENDANT: I didn't. I didn't attempt to defraud. I just was stupid and ignorant.

THE COURT: Okay. But you don't have the intent to commit the crime. If you don't have the intent to commit a crime when you do something, even if it is a crime, you

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aren't guilty. The government has to prove intent.

THE DEFENDANT: I have to rely on these people because I don't --

THE COURT: Okay. Well, you have to rely on me, too, and I can't accept your plea of "guilty" if you didn't intend to do it. You didn't intend to commit a crime if you didn't know it was a crime.

THE DEFENDANT: I didn't want to spend 20 years in jail, though.

THE COURT: Well, I understand, but I can't accept the plea if the person does not believe that they're guilty of committing a crime.

THE DEFENDANT: I am guilty. I am guilty.

THE COURT: No, you're not. You're not telling me what I need to hear to make you guilty. You're not guilty. You said you didn't know it was a crime, you thought it was a gray area and you thought it was legal in Mexico, so it was okay -- You're telling me all these things.

THE DEFENDANT: I am trying not to get myself into more trouble. I am guilty.

THE COURT: Well, I can't accept your plea.

MR. LOUIS: Can I ask a question?

THE COURT: Sure.

THE DEFENDANT: Please.

MR. LOUIS: Miss Branyon, in the plea agreement which I have allocuted to the Court you provided "FM" -- that's identified as "FM" in the plea agreement -- with a form indicating that you were selling these stem cells to him for research purposes?

11:26 THE DEFENDANT: Yes, sir.

MR. LOUIS: And indicate to the Court did you provide him with a form indicating, when you sold him the stem cells, that the stem cells were being used for research purposes?

11:26 THE DEFENDANT: Yes, sir. That was the MPA.

MR. LOUIS: And you knew that he was performing research; you knew that he was actually going to use these stem cells to treat patients?

THE DEFENDANT: I knew that he was both.

11:27 MR. LOUIS: So, when you sent the stem cells, although you provided him with this form that said "For research purpose only" you knew he was not going to be using the stem cells for research purposes.

THE DEFENDANT: I didn't know every -- I knew that he did research, but he didn't -- He would call the office and he didn't tell me, 'Yes, I am using these for research or' -- Should I say this?

THE COURT: Tell the truth.

THE DEFENDANT: I am telling the truth.

11:27 MS. WHALIN: Judge, if I can maybe clarify a

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question, that may help.

MR. LOUIS: Yes. Please do.

MS. WHALIN: In the form that you gave to "FM" to provide to the mothers of the babies who were being birthed, it said "For research purposes only". Correct?

THE DEFENDANT: Yes, ma'am.

MS. WHALIN: When you sent the cells to the gentleman who you sent them to in Brownsville, Texas, you knew that they were being utilized for some research but not only for research. Correct?

THE DEFENDANT: Yes, ma'am.

MS. WHALIN: Okay. Because you also knew that he was using them to actually treat patients in Mexico. Correct?

THE DEFENDANT: Yes. Yes.

MS. WHALIN: Does that clarify, Judge?

THE COURT: But she felt that was a gray area.

THE DEFENDANT: I'm sorry.

THE COURT: She thought because they were being used in Mexico, where it was legal, it was a gray area and, so, therefore, she wasn't -- I mean, there are two parts to it. The first part is you tell the people who are providing the cord blood that this is going to be used for research only, but then, when you get the final product, it's not being used for research only.

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THE DEFENDANT: I'm sorry. Would you repeat that, please?

THE COURT: Sure. As I hear what your attorney is saying and what you are saying -- sort of saying, you went to a provider, a person who was a midwife, and the midwife was purchasing the -- not purchasing -- the mothers were just donating their umbilical cords to this woman, and you provided a document to this midwife saying 'I am accepting these umbilical cords to be used for research only.' Is that right?

THE DEFENDANT: Yes, ma'am.

THE COURT: And you knew that that wasn't true, because, in addition to possible research, they were also going to be used to provide the doctor in Brownsville with medication for his patients in Mexico. Is that right?

THE DEFENDANT: Yes, ma'am.

THE COURT: So, you knew that form was not true; it wasn't wholly being used for research.

THE DEFENDANT: Yes, ma'am.

THE COURT: Is that right?

THE DEFENDANT: Yes, ma'am.

MS. WHALIN: And I think I can get just one more clarification if the Court does need it.

The form that was provided to these mothers that specifically said this was for a donation -- it was not disclosed to the mothers that Miss Branyon was paying the midwife $75 per donation?

THE DEFENDANT: That's true.

MS. WHALIN: And that was not also disclosed to the women who were providing, essentially, this cord blood donation.

THE COURT: And did you know that? Did you know that they were donating them thinking that -- or they were told that their donation would be used for research and, actually, what happened was the midwife did not -- didn't just pass it on to a researcher; she passed it on to you for $75 a cord.

THE DEFENDANT: Yes, ma'am.

THE COURT: Is that right? You knew that?

THE DEFENDANT: The donation went to the doctor for the work that he did, yes, ma'am.

THE COURT: But I am hearing from counsel clarification --

THE DEFENDANT: She's correct.

THE COURT: Wait. Wait. She said that you gave the midwife $75.

THE DEFENDANT: Oh, no, not the midwife.

THE COURT: The midwife sent it to you free. She didn't get any money. You sent it to the doctor --

THE DEFENDANT: Yes, ma'am.

MS. WHALIN: That was a misstatement on my part, the midwife versus doctor. I apologize.

MR. LOUIS: Although Miss Branyon refers to this midwife, it's the same person, a doctor -- She actually paid the owner of the clinic, who was a midwife, who utilized the term "doctor". He was not actually a doctor. And he received the $75.

THE COURT: So, this was a male midwife who was masquerading as a doctor, as an MD doctor?

11:31

11:32 MR. LOUIS: Yes.

THE DEFENDANT: (Indicates negatively)

THE COURT: No? She's saying "No".

THE DEFENDANT: He is a licensed physician in Mexico, but he comes across and does --

11:32 MR. LOUIS: No. We're talking about the owner of the birthing facility. Let's make sure we're clear.

The owner of the birthing facility in Del Rio, Texas -- did you pay the owner of the birthing facility $75 per cord?

11:32 THE DEFENDANT: Yes, sir.

MR. LOUIS: And this is the person that you provided this form to so he could provide the form to the mothers to indicate to them that they were donating their cords for research?

11:32 THE DEFENDANT: Yes, sir.

MR. LOUIS: And the form did not indicate that you were -- that the midwife, who you refer to as a "doctor", was going to be providing the stem cells to you for -- I'm sorry -- providing the cords to you for $75?

11:33 THE DEFENDANT: Correct.

MR. LOUIS: And so, therefore, when the mothers received this form it did not indicate that you would be purchasing the cord blood which you would then, in turn, use to create stem cells and sell to Francisco Morales?

11:33 THE DEFENDANT: Correct. I'm sorry.

THE COURT: Just to make sure I understand. There are two men --

MR. LOUIS: Yes.

THE COURT: -- involved in this. One of them is

11:33 the owner of the birthing facility --

MR. LOUIS: Yes.

THE COURT: -- who is a doctor in Mexico but not a doctor in the United States?

MR. LOUIS: No, Your Honor.

11:33 THE COURT: Or he said he was a doctor in Mexico. I mean, that's what I am hearing her say. But he's really not a doctor.

MR. LOUIS: He's not a doctor.

THE COURT: He's just a businessman who has a

11:33 birthing facility.

MR. LOUIS: He is a licensed midwife --

THE COURT: He is a licensed midwife --

MR. LOUIS: -- in Del Rio, Texas.

THE COURT: -- in Del Rio, Texas.

11:33 MR. LOUIS: Now, that's one person.

THE COURT: Okay. And then we have the second doctor, is the doctor in North Carolina -- no --

MR. LOUIS: Yes.

THE COURT: -- the doctor in North Carolina. And then there is a third doctor who actually used it for treating patients in Mexico?

MR. LOUIS: Yes.

THE COURT: A third individual, male individual, we're talking about?

11:34 MR. LOUIS: Yes, Your Honor. I think she's clarified for me. To make sure the record is correct, I said Columbia. It's actually Charleston --

THE DEFENDANT: Charleston, South Carolina.

THE COURT: South Carolina.

11:34 THE DEFENDANT: I'm sorry for the confusion.

THE COURT: I have just got to get it straight.

Okay. So, you knew that that was wrong, to do that? You knew it was wrong to give a form to the mother saying 'Your umbilical cord is going to be used for research only'?

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11:35 11:35 11:35 11:35 11:36

THE DEFENDANT: I did not know that was wrong. I thought it was correct, because the lab that I had bought from, that's what they -- they gave me the -- that's what they said to do.

I have to tell the truth.

THE COURT: Well, I want you to tell me the truth.

If she didn't know it was fraud to do that, I mean, how can I accept her plea of "guilty" to that crime?

THE DEFENDANT: Oh, please. I need my plea of "guilty". I just have to tell the truth.

MS. WHALIN: Yes. That's correct.

THE COURT: Of course you do.

How about a nolo? Would the government be okay with a nolo?

MR. LOUIS: No.

THE COURT: No nolo?

MR. LOUIS: No, Your Honor. I guess there is no way to proceed forward.

THE COURT: I can't take your plea if you didn't have the intent to commit a crime. I can't do it.

MR. LOUIS: Just so the Court knows, we have gone over this, and it was the government's understanding that the Defendant was acknowledging and admitting that she knew that the stem cells that she was providing to Dr. Morales was not FDA -- had not been created in an FDA-approved facility --

THE DEFENDANT: That is true.

MR. LOUIS: -- had not been -- had not been -- the facility was not FDA-approved --

11:36 THE DEFENDANT: That's true.

MR. LOUIS: -- and that she knew that she could not sell these stem cells to Morales for anything other than research purposes. And since the stem cells were, in fact, sent in interstate commerce, those are the elements of the 11:36 crime. And that's what the government understood that the Defendant was pleading "guilty" to; that she knowingly did those things, that she knew that the cord that she was purchasing from the owner of the birthing facility would be used to create stem cells for the purpose of selling them to 11:37 someone who would use them in the treatment of patients, which, again, was a violation of Title 21, United States Code, Section 331(d). And it was the government's understanding that the Defendant did those things with the intent to defraud knowing that when she was purchasing those 11:37 stem cells that the information provided to the mothers was that it was only going to be for research purposes.

So, that's the facts that the government is relying on. If the Defendant believes that those are not the facts, then we're going to have to move forward.

11:37 MS. WHALIN: And I don't --

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THE COURT: I don't think she's saying she doesn't think that all that happened. I think what she's saying is she didn't know it was against the law to do it. She didn't know it was wrong. She didn't know it was wrong. She didn't know that it was wrong. She didn't have the intent to commit the crime.

MR. LOUIS: And, as the government stands, she did those acts knowing that she could not sell the stem cell purposes -- I mean, sell the stem cells to the gentleman in Brownsville because she knew that they could only be created for research purposes.

THE DEFENDANT: He's correct.

MR. LOUIS: So, therefore, she had the intent to commit the crime because she knew that those stem cells could not be, number one, made outside an FDA-approved facility and, number two, could not be used for anything other than research purposes.

THE DEFENDANT: He's correct, Your Honor. I was just ignorant.

MR. LOUIS: Well, those are two different things.

THE COURT: That's two different things.

MS. WHALIN: Those are two different things.

THE DEFENDANT: He's correct. I want to help. I am so sorry.

THE COURT: No. No.

11:39 THE DEFENDANT: I am begging.

MR. LOUIS: Well, what I ask is that, since we're here, if she wants to have more time to talk with her counsel and then decide. But there is no pressure, certainly, from the government if the Defendant believes that she, in her mind, did not -- I understand the position of the Court and I accept the position as well.

THE DEFENDANT: No. He's correct.

MR. LOUIS: The government doesn't want her to plead to anything that she does not indicate that she committed.

THE COURT: Right.

MS. WHALIN: Judge, if we could have -- I don't believe that Ms. Branyon is disagreeing with anything --

THE DEFENDANT: No.

MS. WHALIN: -- that Mr. Louis is saying. I think that -- and this is just from having constant contact with her. I think there's just some -- If I can just have a couple of minutes to speak with her.

THE COURT: I tell you what. Why don't we -- I have a -- I know this probably is going to be impossible because of airplanes and stuff. I know she's from out of town. She's from Arizona. Right?

MR. LOUIS: That's correct. Both. And counsel.

THE COURT: I really don't -- I have a meeting at

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one o'clock. Why don't we -- I don't think that meeting is going to last very long. Would it be impossible for us to resume this hearing at, say, 2:30?

MS. WHALIN: That's fine with me, Judge.

MR. LOUIS: No, Your Honor. That's fine.

THE COURT: Let's be back at 2:30 and we'll resume.

Before you go, Mr. Louis, has the case been unsealed today by the magistrate?

MR. LOUIS: I filed a motion and it was -- I assume it already had been signed before I came into court. I did not ask Judge Johnson if it had been signed, but it had been filed yesterday, and I didn't ask. But to the extent that it was not, which I assume it was signed and unsealed, the government certainly moves that it be unsealed.

THE COURT: I will unseal it if Judge Johnson hasn't already done that. May I do that?

MR. LOUIS: She had a copy of it; so, I assume that --

CASE MANAGER: Because there's nothing on CM/ECF at all and it takes some time to get it on there. I just wanted to confirm for his purposes as well.

MR. LOUIS: Thank you.

THE COURT: All right. Thank you.

(Recess)

THE COURT: All right. This is a continuation of

Criminal No. H-11-535, United States v. Fredda Branyon.

Ms. Whalin.

MS. WHALIN: Judge, I think that I had an opportunity to speak with Ms. Branyon. She did indicate to me that there was some confusion. She was very nervous when she was in here. So, I think we can go forward with the factual basis with respect to -- and I think the only focus that, really, we need to look at is the third element of whether or not she intended to either mislead or defraud anybody in this criminal act, and specifically here would be the women at the birthing center who were donating the cord blood.

So, I think at this point -- I don't know if counsel wants to lay the factual basis, if we want --

MR. LOUIS: Well, this is a continuation from the previous setting. I think the Court has had the factual basis. I will just summarize them again.

The factual basis that's laid out in the plea agreement indicates that Miss Branyon had a company -- I won't go over -- the name of the company was Global Labs, and Miss Branyon then sold stem cells over the -- using interstate commerce to a person, and I have identified him, because he's not associated with this criminal information, by just initials --

THE COURT: Right.

MR. LOUIS: -- which is part of our policy, but identified as "FM". That individual then used the stem cells to treat patients. Ms. Branyon's company was not an FDA-approved facility and Ms. Branyon did not obtain FDA approval to either sell the stem cells or in any way conduct research to sell the stem cells.

In connection with the scheme, Miss Branyon also purchased cord blood from an individual identified as "AR" who had a birthing facility in Del Rio, Texas, and Ms. Branyon paid "AR" for the cords that she intended to use to create stem cells. She did, in fact, provide those cords to a person that's identified as "VD", who was a professor with a medical school in Charleston, South Carolina. Those cords were provided to "VD" for the purpose of creating stem cells, viable stem cells, which on occasion "VD" was able to do and, in fact, provided those to Ms. Branyon, which, in turn, were going to be sold to "FM" and others to treat patients. And this was all done with the intent to defraud.

THE COURT: All right. Is that correct, Miss Branyon?

THE DEFENDANT: Yes, ma'am. I didn't quite understand all of the wording, but he is correct. When you're nervous you're nervous.

THE COURT: I know. I understand. I understand.

Fredda Branyon, how do you plead to Count 12 of the criminal information? Guilty or not guilty?

THE DEFENDANT: Guilty.

THE COURT: All right. Would you then execute the plea agreement.

14:41 (Document signed by counsel and the Defendant)

THE COURT: Ms. Branyon, is that your signature on the plea agreement?

THE DEFENDANT: Yes, ma'am. Sorry for the confusion.

14:42 THE COURT: That's okay. Don't worry about it.

It is the finding of the Court in the case of United States v. Fredda Branyon that the Defendant is fully competent and capable of entering an informed plea, that the Defendant is aware of the nature of the charges and the 14:43 consequences of the plea and that the plea of "guilty" is a knowing and voluntary plea supported by an independent basis in fact containing each of the essential elements of the offense. The Defendant is now adjudged guilty of that offense.

14:43 Miss Branyon, as I told you, a presentence report will be prepared to assist me in sentencing. You will be asked to give information for that report, and Ms. Whalin may be with you when you are interviewed by the probation officer.

14:43 By October 7th, 2011, the initial presentence report will be disclosed to counsel. By October 21st, 2011, counsel shall file either objections in writing to the facts of the offense and application of the sentencing guidelines or a statement that there is no objection. By November the 4th, 2011, the probation officer shall submit to the judge the final presentence report with an addendum addressing contested issues.

14:43

Sentencing is set for November the 18th, 2011, at 10:00 a.m.

14:44 Is there anything else?

MR. LOUIS: No, Your Honor, not that I can think of.

MS. WHALIN: Can we address the passport issue?

MR. LOUIS: Yes. Ms. Branyon has -- or is undergoing medical procedures and she has scheduled procedures coming up which is outside the U.S. This was brought to the attention of Magistrate Judge Nancy Johnson, which she indicated that the pretrial services officer will maintain her passport and that, if she needed to travel, she just needs to provide information to pretrial services, which will then contact me and then, if there's an issue, bring it to the Court's attention.

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MS. WHALIN: Judge, in addition to that, Ms. Branyon's employment is outside of the United States.

14:45 THE DEFENDANT: I need to work.

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MS. WHALIN: We are asking the Court to allow her to work -- utilize her passport for work purposes under the same guise that she contact pretrial services to request the passport to allow her to work. It's not an everyday occurrence that she's outside of the United States for work. So, we would ask the Court to allow her to leave the country for work purposes, specifically going to Mexico.

THE COURT: I will allow that. She needs to notify the pretrial services officer and, you know, be specific about where she's going to be and how long she's going to be there and whatever other stipulations, such as calling in and things like that, which I think they do sometimes when people have to leave the country.

MS. WHALIN: Thank you, Judge.

THE COURT: That's fine with me.

MS. WHALIN: Okay. And this travel -- we would also ask -- and although the travel is less frequent to Panama, she does have a company there as well. Would that go for the same --

THE COURT: Yes.

MS. WHALIN: Just contact pretrial services to inform them?

THE COURT: Yes.

MS. WHALIN: Thank you, Judge.

THE DEFENDANT: Thank you, Your Honor.

THE COURT: That presupposes that she remains on bond.

MS. WHALIN: Absolutely.

THE DEFENDANT: I am not going nowhere.

14:46 THE COURT: Okay. Well, just be sure you check in and just let the pretrial services know about your whereabouts at all times if you're going to be out of the country.

MR. LOUIS: And the government will say in not so much detail, but give some specificity as to --

14:46

THE COURT: Exactly where and how you can be contacted.

THE DEFENDANT: I will give you everything.

Thank you all very much. Sorry to make you come back.

14:46

MS. WHALIN: Thank you for accommodating us.

COURT REPORTER'S CERTIFICATE

I, BRUCE SLAVIN, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter, to the best of my ability.

s/Bruce Slavin
BRUCE SLAVIN, RPR, CM